CONTROLLED SUBSTANCES (PHARMACY STOCK)

1. **REASON FOR ISSUE**: This Veterans Health Administration (VHA) Handbook provides procedures for maintaining accountability of all controlled substances and compliance with Drug Enforcement Administration (DEA) regulations.

2. **SUMMARY OF MAJOR CHANGES**: This VHA Handbook incorporates requirements regarding the perpetual inventory which must be maintained for all controlled substances.

3. **RELATED DIRECTIVE**: VHA Directive 1108, to be published.

4. **RESPONSIBLE OFFICE**: The Chief Consultant, Pharmacy Benefits Management Strategic Health Group (119) is responsible for the contents of this Handbook.

5. **RESCISSIONS**: This VHA Handbook rescinds VHA Manual M-2, Part VII, Chapter 5, dated May 4, 1995; and VHA Directives 10-91-107, and 10-93-011.

6. **RECERTIFICATION**: The document is scheduled for recertification on/or before the last working day of May 2002.

S/ Thomas Garthwaite, M.D., for
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Under Secretary for Health

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CONTROLLED SUBSTANCES (PHARMACY STOCK)

1. PURPOSE

This Handbook defines procedures for the Department of Veterans Affairs (VA) accountability of all controlled substances and compliance with Drug Enforcement Administration (DEA) Regulations.

2. SCOPE

a. VA maintains perpetual inventory of all controlled substances. These items will consist of the drugs and other substances by whatever official name, common or usual name, chemical name, or brand name designated, listed in Title 21 Code of Federal Regulations (CFR) Part 1300:

(1) Schedule II drugs are found in 21 CFR 1308.12,

(2) Schedule III drugs are found in 21 CFR 1308.13,

(3) Schedule IV drugs are found in 21 CFR 1308.14, and

(4) Schedule V drugs are found in 21 CFR 1308.15.

b. These substances will be inventoried according to DEA regulations as found in 21 CFR 1304. A biennial inventory of all controlled substances will be conducted and records maintained in accordance with 21 CFR 1304.13.

c. Prescriptions and the completed VA Form 10-2320, Schedule II, Schedule III Narcotic and Alcoholics Register, and VA Form 10-2321, Controlled Substance Order, will be retained and securely stored. Disposal will be only in accordance with Veterans Health Administration (VHA) Records Control Schedule 10-1.

d. All prescriptions for controlled substances will be dated as of, and signed on, the day when issued and will bear the full name and address of the patient, and the name, address, and DEA registration number of the practitioner. Prescriptions should not be filled if they are more than 7 days old when presented.

e. An intern, resident, mid-level practitioner, foreign-trained physician, physician, or dentist on the staff of a VA facility exempted from registration (21 CFR 1301.24) will include on all prescriptions issued the registration number of the VA facility and the special internal code number assigned by the VA facility in lieu of the registration number of the practitioner required by law (21 CFR 1306.05b). Each written prescription will have the name of the physician or authorized practitioner stamped, typed, or hand printed on it, as well as the signature of the physician or authorized practitioner.

f. The label of any drug listed as a "Controlled Substance" in Schedule II, III, IV, or V of the Controlled Substances Act will, when dispensed to or for a patient, contain the following

warning: "CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."

g. All prescriptions for controlled substances will be stamped with the letter "C," in red ink, not less than 1 inch high, in the lower right corner, in accordance with 21 CFR 1304.04.

h. A perpetual inventory of all pharmacy stock of all schedules of controlled substances will be maintained and verified by Pharmacy Service at a minimum of every 72 hours. Documentation of the verification will be made on the appropriate VA Form 10-2320, or electronic equivalent. These inventories will be inspected during the monthly unannounced narcotic inspection.

i. Each facility will limit the number of pharmacy employees who have access to scheduled drugs in the pharmacy within a 24-hour period to less than ten per storage site. Pharmacy Chiefs must establish access limits based on workload requirements for dispensing controlled substances.

j. Pharmacy Service will verify the identity of the person picking up the outpatient controlled substance prescription for outpatients and patients leaving the hospital, and must require the signature of such person or their agent.

k. All outpatient prescriptions for controlled substances not picked up at the outpatient window will be returned to stock or mailed to the patient ensuring strict accountability. Pharmacy Service will develop policies that address this issue.

l. For all outpatient prescriptions not dispensed in an original manufacturer’s container that contains a tamper-proof seal, Pharmacy Service will affix a tamper-proof seal on the completed prescription vial for all controlled substance outpatient prescriptions.

m. All current and new Pharmacy employees will be required to view the video “Employee Integrity and Pharmacy Security” as part of employee orientation, and as needed as determined by the Chief, Pharmacy Service. Documentation that this requirement is met is maintained in Pharmacy Service.

n. In the temporary absence of the Chief, Pharmacy Service, the facility pharmacist designated as Acting Chief, will automatically assume responsibility for security and control of controlled substances.

(1) On permanent change of facility, or when a relief pharmacist is temporarily in charge of Pharmacy Service, a complete inventory will be conducted.

(a) This inventory will be conducted by the incoming Chief or pharmacist temporarily in charge, jointly with the appointed facility inspecting official.

(b) A record of the inventory will be made on VA Form 10-2320 for each drug inventoried and will be signed by the outgoing and incoming Chief (or Acting Chief) and the facility inspecting official.

(2) Any discrepancy will be made a matter of record and, if indicated, an investigation made to determine the cause of the discrepancy.

NOTE: *More stringent controls will be developed at the local facility if deemed necessary by the Chief, Pharmacy Service.*

o. Orders for Scheduled II and Schedule III narcotic substances to be administered to patients from unit dose or ward stock will be written for periods not to exceed 72 hours. Exceptions may be made if the responsible practitioner has evaluated the patient's condition and determined there is a need for a longer duration of therapy. In such cases, the practitioner may prescribe for a period not to exceed l4 days if the practitioner indicates a specific length of therapy or number of doses in the individual patient's order.

3. STORING CONTROLLED SUBSTANCES

a. All Schedule II and Schedule III narcotics and bulk supplies of Schedule III non-narcotic, Schedules IV and Schedule V controlled substances, and Schedule V substances will be secured as defined in MP-1, Part I, Chapter 2, Section B. Storage of bulk controlled substances will be in the main pharmacy vault, or other limited access locked room or cabinet. Controlled substances will not be stored in the warehouse.

b. Dispensing stock of Schedule III non-narcotic, Schedule IV, and Schedule V controlled substances will be stored and dispensed in locked areas and not dispersed with general pharmacy stock.

c. All outpatient controlled substances awaiting patient pickup will be stored in a locked area, i.e., cabinet. Employees having access to the locked area will be limited and documentation of access will be maintained by the Chief, Pharmacy Service.

d. Each medical center and outpatient clinic must install electronic access control systems in pharmacies to monitor access to controlled substances. This includes vaults and cabinets used for storage of controlled substances within pharmacies, and secured areas utilized for dispensing of controlled substances within pharmacies.

e. The following specifications are among those to be considered for inclusion in any access control system:

(1) Access Safeguard. To prevent learning codes through keypad observation or use of stolen or found access cards.

(2) Time Sensitive. The ability to program access by user by shift, and day.

(3) Area Sensitive. The ability to program access by door and area for each individual user.

(4) Fail-Safe. The ability to maintain access security if the system goes down (i.e., bypass key).

(5) Access Record and/or Audit Trail. The ability to provide for periodic or on demand print-out of names and time/dates of individual accessing.

(6) User Coverage. The number of individual access codes that the system will accommodate.

4. ORDERING AND RECEIVING CONTROLLED SUBSTANCES

Medical centers will establish written procedures for the ordering and receipt of controlled substances. These procedures will indicate the individuals from Acquisition and Materiel Management Service (A&MMS) and Pharmacy Service who are designated the authority and responsibility to order, receipt, post, and verify.

a. **Ordering Controlled Substances**

(1) All controlled substances will be ordered separately from non-controlled substances, and in compliance with 21 CFR 1300 to end.

(2) The delivery address on all orders for controlled substances will be the individual pharmacy.

b. **Receiving Controlled Substances**

(1) All orders for controlled substances will be delivered directly to pharmacy in unopened shipping cartons (boxes).

(2) The opening of the cartons and the acknowledgment of receipt of the order will be performed in the pharmacy and witnessed by the accountable officer, or designee, and the responsible pharmacy employee.

(a) Receipt will be annotated on the appropriate forms by both employees.

(b) The accountable officer or designee will verify that receipt of the controlled substance has been posted to pharmacy inventory and annotate the verification on the appropriate forms.

NOTE: *Discrepancies will be reconciled with the accountable officer, or designee, before items are accepted by the pharmacy.*

5. CONTROLLED SUBSTANCES ORDER DISPENSING

a. **Inpatient Dispensing for Controlled Substances that Require Perpetual Inventory**

(1) Unit Dose

(a) Orders for controlled substances will be written by the physician on VA Form 10-1158, Doctor's Orders (set), or another approved form.

(b) Orders for controlled substances will be serially numbered with appropriate entries made on appropriate inventory records as VA Form 10-2638, Controlled Substance Administration Record, VA Form 10-2320, or an alternate computer generated entry.

(c) Orders will be filed in a readily retrievable patient's medication profile or maintained through computer entry.

(d) Each dose will be identified by:

1. Name,

2. Form and strength,

3. Control number, and

4. Expiration date.

(e) Controlled substances for each patient will be delivered and dispensed at scheduled times, in a suitable container which identifies each patient by name, or from an automated dispensing system. The container will be stored in a double locked cart. An automated dispensing system must maintain appropriate records and controls.

(f) Authorized nursing personnel will sign for controlled substance delivery.

(g) Posting of all unused doses will be made by Pharmacy Service.

(2) Automatic Replenishment

(a) Appropriate levels consistent with the needs of the using ward or clinic will be established.

(b) A supply of controlled substances will be issued to wards and clinics by an authorized pharmacy employee. An appropriate record will be made and maintained in the pharmacy of each item issued.

(c) The authorized pharmacy employee, in the presence of the authorized nursing personnel, will note the balance on hand from VA Form 10-2638, or other approved form(s), and replenish enough of each item to reach established levels.

1. On the first unused line of VA Form 10-2638, the same serial number as on VA Form 10-2321 will be entered in "Name of Patient" column. The amount replenished will be indicated in the "Dose" column. This amount will be added to the amount indicated in the "Balance" column of the line above. The authorized nursing personnel and the pharmacy employee will both sign in the "Administered By" column.

2. Pharmacy Service will prepare a VA Form 10-2321 for each item replenished. VA Form 10-2321 will indicate the name, ward or clinic, strength, and amount of drug replenished. Forms will be in ink or typewritten and serially numbered. ***NOTE:*** *The authorized nursing personnel will sign for controlled substances.*

3. VA Form 10-2638 for each item will be numerically numbered in a continual sequence. When a form is completed, the pharmacy employee will prepare a new form with the last balance of the completed form carried over to the beginning of new form.

4. On return to the pharmacy, the issuing pharmacy employee will "tally" the amounts issued against the amounts replenished (using VA Form 10-2321 returned by the pharmacy employee). Remaining items will be returned to stock. Appropriate entries will be made on VA Form(s) 10-2320.

(d) A list of ward and clinic issues will be maintained by the pharmacy indicating series number, date, and amounts issued to each ward and clinic.

(e) Completed VA Form 10-2638 may be retained on the ward or clinic in separate folders, or separate sections if one binder is used, until picked up by authorized personnel. Each completed VA Form 10-2638 returned will be reviewed by a pharmacy employee prior to filing, for arithmetic, losses, or unusual waste. ***NOTE:*** *Discrepancies will be handled as stated in paragraph 8.*

(f) Controlled substances returned from wards and clinics and determined by Pharmacy Service to be suitable for reissue will be returned to stock. Appropriate entries will be made on VA Form 10-2320 and VA Form 10-2638.

(g) Computerized Automatic Replenishment Systems may be utilized as long as they comply with 21 CFR Part 1300 to end.

(3) Clinic or Ward Stock

(a) Controlled substances will be dispensed on VA Form 10-2321, prepared in duplicate, or electronic equivalent in the Decentralized Hospital Computer Program (DHCP). Orders will be limited to one package per item per form. Forms will be completed in ink or typewritten, and original only will be signed by a physician, dentist, or registered nurse (R.N.). The duplicate

copy will be marked "duplicate" and retained on the ward. The duplicate will be checked for verification at the time of delivery.

(b) Orders for controlled substances will be filled by an authorized pharmacy employee.

(c) VA Form 10-2321, or electronic equivalent will be serially numbered, dated, and signed.

(d) VA Form 10-2638, or electronic equivalent will accompany each container issued.

(e) A serial number corresponding to the number assigned the order on VA Form 10-2321 will be placed in the appropriate space on VA Form 10-2638.

(f) Pharmacy Service will maintain a list of wards and clinics indicating serial numbers of all VA Forms 10-2638 issued during the preceding months, as well as those carried over from previous inspections.

1. The list must include the name, strength, and amount of the drug issued.

2. This list may be kept manually or through a computerized system.

(g) Controlled substances must be dispensed and delivered by the authorized pharmacy employee for delivery to wards and clinics. A temporary record will be maintained in pharmacy until the employee returns with the signed VA Form 10-2321 or electronic equivalent.

(h) On receipt of the controlled substances and the accompanying record forms, the authorized employee(s) making delivery to the ward or clinic will:

1. Check receipts for accuracy with the items and quantity appearing on VA Form 10-2321, or electronic equivalent.

2. Check the serial number of VA Form 10-2638 against the serial number of VA Form 10-2321, or electronic equivalent.

3. Sign and date receipt on VA Form 10-2321 or electronic equivalent.

4. On return to the pharmacy, the authorized employee will return the signed VA Form 10-2321, and the records will be cleared.

(i) When controlled substances are delivered to the ward by the authorized employee(s), the R.N. will check the drugs and record forms for accuracy, and sign for receipt of VA Forms 10-2321 or electronic equivalent.

1. If discrepancies exist between the amount ordered and the amount received, the R.N. will check with the designated pharmacy employee concerning the amount issued.

2. If the discrepancy is not resolved, reports will be made immediately, through the responsible supervisors, to the medical center or clinic Director for investigation and necessary action.

(j) Completed VA Forms 10-2638 returned from wards and clinics will be canceled from the list and filed in separate folders, or separate sections if one binder is used. Each completed VA Form 10-2638 returned will be reviewed by a designated pharmacy employee prior to filing for arithmetic, losses, or unusual waste. Discrepancies will be referred as soon as practicable, through the responsible supervisor, to the Controlled Substances Inspecting Official, medical center or clinic Director for investigation and necessary action.

(k) Until DHCP software is available, a computerized system may be utilized as long as it complies with Federal Regulations and VA Central Office policy.

(4) Compounded Schedule II and Schedule III Narcotic Substances

(a) Compounded Schedule II and Schedule III narcotic substances, intravenous or oral, etc., will be ordered on VA Form 10-2577F, Security Prescription Form, or on VA Form 10-1158,

(b) The order will be handled according to subparagraphs 5a(1)(b) through (g).

(c) When Schedule II and Schedule III narcotic substances are used in bulk compounding stock preparations for later issue, the pharmacist will complete VA Form 10-2321, which will serve as a bulk compounding record, indicating the name and quantity of the Schedule II and Schedule III narcotic substances used, and the name and quantity of preparation to be compounded. The form will be:

1. Prepared in ink or typewritten,

2. Serially numbered,

3. Dated,

4. Signed by the pharmacist issuing the Schedule II and Schedule III narcotic substances, and

5. Initialed by the individual using the substances.

NOTE: *Appropriate entries will be made on VA Form 10-2320.*

b. **Outpatient Services**

(1) Controlled substances for individual patients will be ordered on properly completed VA Form 10-2577F, VA Form 10-1158, or other approved form, and filled in compliance with 21 CFR 1306.

(2) Partial outpatient dispensing of Schedule II, narcotic substances, may be done as long as it is in compliance with 21 CFR 1306.13 and VA Central Office policy. The Pharmacy and

Therapeutics Committee must establish policies for identifying patients as terminally ill and eligible for partial dispensing of Schedule II narcotic substances.

(3) Controlled substance prescriptions must be filed in accordance with 21 CFR 2304.04.

(4) Prescriptions written for controlled substances filled by VA pharmacies may be mailed in compliance with 21 CFR 1300 to end, VA policy, and United States (U.S.) Postal Regulations.

(5) The refilling of a prescription for a controlled substance listed as Schedule II is prohibited in compliance with 21 CFR 1306.12.

(6) Schedule III through Schedule V controlled substances may be refilled in compliance with 21 CFR 1306.22.

(7) Partial filling of Schedule III-V controlled substances will be in compliance with 21 CFR 1306.23.

6. METHADONE MAINTENANCE TREATMENT PROGRAM

NOTE: *Facilities must be licensed for this program. See Federal Drug Administration (FDA) Regulations, 21 CFR 310.305.*

a. **Ordering and Storage**

(1) Pharmacy stock requirements of methadone for a maintenance program will be ordered separately from other Schedule II and Schedule III narcotic substances on VA Form 90-2138, Order for Supplies or Services, or VA Form 90-2237, Request, Turn-In, and Receipt for Property or Services.

(2) Only oral, liquid dosage form, or specially formulated dispersible tablets, will be utilized for a treatment program. The final oral dose administered to the patient will be in oral liquid form.

(3) Methadone for the maintenance treatment program will be stored according to Federal Regulations and VA policy.

b. **Dispensing**

(1) Methadone for maintenance treatment will be dispensed on receipt of VA Form 10-2577F, VA Form 10-1158, or other approved form, written by a physician who has submitted a FDA Form FD-2633, Medical Responsibility Statement for Use of Methadone in a Treatment Program. ***NOTE:*** *This FDA Form is available from FDA.*

(2) Methadone will be packaged and dispensed in a single dose form conforming to Public Law 91-601, "Poison Prevention Packaging Act of 1970," and subsequent amendments.

(3) Each take home dose will be dispensed in a child resistant container and will be labeled with the:

(a) Treatment center's name,

(b) Address,

(c) Telephone number, and

(d) Physician's name.

7. RECORDS AND FORMS

a. Receiving documents for all controlled substances must be maintained separately from all other receiving records.

b. Completed VA Form 10-2321, for ward stock orders will be filed separately in a numerical file.

c. Completed VA Form 10-2577F, or other approved forms for Schedule II controlled substances dispensed to outpatients, will be filed separately in a numerical file or according to 21 CFR 1304.04.

d. Schedule II narcotic substances and Schedule II non-narcotic substances entered into the DHCP Pharmacy software package will be coded in the “DEA Special Handling” fields designated 2A and 2L.

e. Schedule III through V controlled substances entered into the DHCP Pharmacy software package will be coded in the "DEA Special Handling" fields, designated 3 through 5 (L, A, B, C).

f. Alternate methods and systems of maintaining records and forms for controlled substances may be developed, utilizing computerized systems, as long as they comply with 21 CFR 1300 to end.

g. Each facility will maintain records on personnel authorized access to areas where scheduled drugs are stored. Dispensing and records keeping may be delegated to technical personnel under the direct supervision of an assigned pharmacist. This pharmacist must sign all records of receipt and dispensing.

8. PROCEDURE IN CASE OF LOSS OF CONTROLLED SUBSTANCES

a. In cases of accidental loss, breakage, or destruction of small quantities of Schedule II through Schedule V substances (such as single doses), the appropriate controlled substances record will be balanced and a brief explanation of the circumstances entered on VA Form 10-2320 or Form 10-2638, as indicated.

(1) Entries and explanations will be signed by the person responsible for the loss or breakage and called to the attention of the immediate supervisor, at the earliest opportunity.

(2) The immediate supervisor will countersign VA Form 10-2638 and VA Form 10-2320. If the explanation is not considered satisfactory by the immediate supervisor, the incident will be reported to the facility Director for investigation and necessary action to prevent recurrence.

b. In cases of recurring shortages, loss of significant quantities of Schedule II-V substances (several doses), or if there is indication of theft, a report will be made to the facility Director, and a DEA Form 106, Report of Theft or Loss of Controlled Substances, will be completed in accordance with 21 CFR 1301.74. Losses disclosed during monthly inspections will be reported to the facility Director by the inspecting official.

c. Any suspected theft, diversion or suspicious loss of drugs must be immediately reported by the medical center Director, to the:

(1) Office of the Inspector General,

(2) Office of Investigations, and

(3) Facility police.

d. All facilities will report the theft, loss or suspected diversion of any controlled substance or high value drug through the Regional Director to the Chief Consultant, Pharmacy Benefits management Strategic health Group (119). The following information must be included in the report to the Regional Director:

(1) Date(s) or approximate date(s) of each incident.

(2) Description of each action planned or taken to prevent future loss/theft of drugs.

(3) Date each action in subparagraph d(2) was completed.

(4) For each incident in subparagraph d(1) provide:

(a) Generic name of each, controlled substance schedule (if appropriate), and total quantity for each drug stolen or lost.

(b) Date on which VA initially became aware of theft or loss.

(c) The means by which VA first became aware of the theft or loss.

(d) The agency or service that initially discovered the theft of loss.

(e) The agency or service initially reporting the theft or loss to VA

(f) Each agency known to have investigated the theft or loss.

(g) List all law enforcement agencies (Federal Bureau of Investigation (FBI), DEA, local, State, VA police, etc.) to which the incident was reported by VA.

(h) Indicate the category of the suspect, if known:

1. Current VA employee,

2. Former VA employee,

3. Current VA patient,

4. Former VA patient,

5. Current VA volunteer,

6. Former VA volunteer, or

7. Unknown.

(i) If the suspect identified was a VA employee, provide:

1. Suspect's employment class,

2. Suspect's employment series,

3. Suspect's grade, and

4. Suspect's occupational group.

e. In case of suspected loss by substitution, the medical center Director will direct that the suspected material be analyzed by a qualified analyst. Adjustment will be made in the appropriate record by the facility Director, or designee, for quantities used in the testing procedure. If substitution is confirmed, an immediate investigation will be conducted and the loss will be reported as outlined in subparagraphs c and d.

f. Upon completion of the investigation, quantities of Schedule II through Schedule V substances lost for analysis, or otherwise removed from stock in connection with the investigation involved, will be dropped from the record with an appropriate written explanation

opposite the entry. Records will be balanced and all entries and explanatory remarks will be signed by the facility Director, or designee.

9. DISPOSITION OF EXPIRED OR EXCESS CONTROLLED SUBSTANCES

a. Pharmacy Service will establish an "unusable controlled substance ledger" using DEA Form 41, Registrants Inventory of Drug Surrender, or other appropriate form. All controlled substances returned from ward, clinic, patient or from pharmacy stock that is determined unusable and to be destroyed will be posted on the ledger with appropriate information indicated on the ledger. The "unusable controlled substance ledger" and the sealed bags of the unusable controlled substances will be checked monthly by the narcotics inspector. The inspector will verify the accountability of the sealed bags on the ledger. The contents will be verified at the time of destruction.

b. Excess controlled substances in wards and clinics will be returned to Pharmacy Service for redistribution, or turn-in, and items determined unsuitable for reissue by Pharmacy Service, will be accepted in the pharmacy for storage purposes only, prior to acceptance by the Chief, A&MM Service, for disposal. The following procedure will be used:

(1) The R.N., or other health care professional, will prepare, in duplicate, VA Form 10-2321 for each controlled substance turned in for disposition. The form will be prepared in ink or typewritten and will be clearly marked "Turn-in Slip." The following information will be included:

(a) Designation of ward or clinic;

(b) Date;

(c) "Believed" or "purported" identity of the controlled substances;

(d) Size, strength, etc., of the controlled substances;

(e) Quantity; and

(f) Signature of R.N.

(2) The R.N. will take to the pharmacy:

(a) The controlled substance to be returned,

(b) VA Form 10-2321 prepared in duplicate in accordance with subparagraph 9a(1) and

(c) VA Form 10-2638 for the controlled substances being returned.

(3) The authorized pharmacy employee will check the alleged controlled substances in the presence of the R.N., or other health care professional, and will place each item returned in a separate envelope.

(a) The date, name of substance "believed" or "purported" to be returned, and quantity will be written in ink or typewritten on each envelope.

(b) Each envelope will be dated, sealed, and signed across the seal by the authorized pharmacy employee and the R.N.

(c) The closure of the envelope will be reinforced with clear cellophane tape covering the signatures.

(d) The sealed drugs will be stored in the pharmacy safe or vault apart from other drugs or current stocks.

(e) The return of the substance will be posted on the "unusable controlled substance ledger" by the authorized pharmacy employee.

(4) The authorized pharmacy employee will date and sign receipt on the original and duplicate of VA Form 10-2321 and return the original to the nurse as a receipt for the drug and VA Form 10-2638. If applicable, the duplicate will be retained in the pharmacy in an "Excess Controlled Substance File."

(5) VA Form 10-2638 will be completed using the following instructions:

(a) Date in the "Date" column.

(b) "Return to Pharmacy for disposition" in "Name of Patient" column.

(c) Signature of R.N. and Controlled Substances Inspecting Official in "Administered By" column.

(d) Entries will be made on the line following the last entry for administration of the substances.

(e) VA Form 10-2638 will be canceled by drawing a diagonal line across the remainder of the sheet.

c. Excess or unusable controlled substances will be removed from pharmacy's stock at the time of the regular monthly inspection and posted in the "unusable controlled substance ledger." The date, reason, and amount removed from pharmacy stock will be indicated on VA Form 10-2320. The form will be signed by the Chief, Pharmacy Service, or designee, and the Controlled Substances Inspecting Official. Each item removed from stock will be placed in an envelope as described in subparagraph 9b(3), but will be signed by the Chief, Pharmacy Service, or a designee, and the Controlled Substances Inspecting Official. ***NOTE:*** *VA Form 10-2320 will be retained in the "Excess Controlled Substance File."*

d. Controlled substances returned by patients and family members and those returned by the U.S. Postal Service and determined not suitable for reissue will be placed in an envelope, one item per envelope as described in subparagraph 9b(3), but will be signed by a supervisory pharmacist and a staff pharmacist. Items will be posted on a ledger, list, or automated file of controlled substances waiting for disposal. ***NOTE:*** *VA Form 10-2320 is to be completed and retained in the "Excess Controlled Substance File."*

e. Controlled substances returned by the U.S. Postal Service as undeliverable and those not picked up by patients at the pharmacy window will be returned to pharmacy stock if determined to be suitable for reissue. VA Form 10-2320 will show date, prescription number, patient's name, quantity returned to stock, and inventory adjustment. A supervisory pharmacist and a staff pharmacist will sign on the next unused line as witnesses to the transaction. The patient's prescription will be marked "returned to pharmacy stock," dated, and signed by the supervisory pharmacist and staff pharmacist.

f. Each envelope will be given a consecutive serial number when prepared for storage. Each controlled substance will be entered on DEA Form 41, along with the corresponding serial envelope number. ***NOTE:*** *The number of containers, contents, and units must be completed.*

g. A copy of DEA Form 41 will be attached to VA Form 90-2237 as a "turn-in." VA Form 90-2237 will state: "See Attached List of Controlled Substances for Turn-in."

h. All expired or excess controlled substances will be stored in the pharmacy vault or safe until final disposition is made.

i. At least quarterly, unusable controlled substances will be turned in to the Chief, A&MM Service, for disposition. The disposition will be witnessed and attested to by the Chief, A&MM Service or designee, the Chief, Pharmacy Service, or designee, and Controlled Substances Inspecting Official. At least 15 days prior to the proposed date of destruction, the DEA Form 41 must be forwarded to the DEA division, or resident office, which serves the geographic region in question. The form must be accompanied by a statement as to the proposed date and time of destruction, the method of disposal, the names of the two individuals who will witness the procedure, and the exact location at which the procedure will take place. If no response is received from the DEA office after the 15 days has elapsed, the controlled substance may be destroyed. Once the process has been completed, the DEA Form 41 must be signed, dated and forwarded to the appropriate DEA office for filing.

j. When it is necessary to "waste" part of a Schedule II or Schedule III narcotic substance unit on the ward or clinic, two entries will be made.

(1) The first entry will be the dose given (one-half ampule, 25 mg., etc.).

(2) The second entry will be the amount wasted (one-half ampule wasted, 25 mg. wasted, etc.).

(3) An R.N. may waste a partial dose of a Schedule II or Schedule III narcotic substance. The wasting of the dose must be witnessed by an authorized nursing employee. The amount "wasted" will be disposed of in an appropriate manner.

k. Disposal of excess of expired Schedule III, IV, and V substances will be in accordance with DEA Regulations, 21 CFR 1307.21, MP-2 108-43.309 and MP-2 108-43.313-1.

10. CONTROLLED SUBSTANCES IN RESEARCH AREAS

a. **Procurement.** All controlled substances for use in research (animal or human) will be ordered on VA Form 90-2237 through Pharmacy. All controlled substances will be ordered separately from non-controlled substances. The drugs will be charged to the appropriate research cost control point.

b. **Issue**

(1) On receipt, Pharmacy Service will issue the drug to the appropriate research area. The drugs will be charged to the appropriate research cost control point.

(2) Issuance of controlled substances to research areas will be in accordance with the general provisions for dispensing controlled substances outlined in paragraph 5. Persons authorized to receive controlled substances will be designated by the medical center Director on the advice of the Associate Chief of Staff for Research, or the Chief of Staff.

c. **Control**

(1) One VA Form 10-2638, will accompany each container issued.

(2) Authorized employee(s) in the research areas will maintain appropriate records in accordance with the provisions of this chapter.

(3) VA Form 10-2638 will indicate the experiment number, date, and any other identifying information available to provide satisfactory proof-of-use record for each dose of drug administered.

d. **Inspection**

(1) VA Form 10-2638 and the corresponding drug will be made available for monthly inspection by the appointed Controlled Substances Inspecting Official.

(2) VA Form 10-2638 when completed, will be returned to the pharmacy.

e. **Storage**

(1) All controlled substances must be secured as MP-1, Part I, Chapter 2, Section B.

(2) Access will be limited to employees specifically authorized in writing to have access to the controlled substances.